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10/551,989

10/04/2005

Josep Vicent Mercader Badia

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EXAMINER

HOBBS, LISA JOE

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

05/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/551,989 | Applicant(s) MERCADER BADIA ET AL. | |
| | Examiner Lisa J. Hobbs | Art Unit 1657 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>14 December 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 25 January 2008 is acknowledged. The traversal is on the ground(s) that some common subject matter is shared between the independent claims 1, 6 and 7. This is not found persuasive because although some common subject matter may be shared, the groupings in Lack of Unity requirements, see PCT Annex B, section (e) citing Rule 13.2, allow for one method and one product specially designed for carrying out that process in one group. A second method, particularly one that requires a different examination and analysis since the temperatures are applied to a different container than specified in group I and are applied in a different sequence, and a second product are not properly included with the first named method and the first product specially designed for carrying out that process.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 07 April 2003. It is noted, however, that IB has not filed a certified copy of the French application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The information disclosure statement(s) (IDS) submitted on 14 December 2005 is/are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Status

Claims 1-11 are active in the case. Claims 1-5 and 11 are under examination; claims 6-10 are withdrawn as drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1657

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holbrook (EP 0 295 116), Taylor et al. (WO 2000/63668) and Grant et al. (US 5624815). Holbrook teaches apparatus and methods for microorganism culture and testing comprising liquid medium in a Stomacher device (page 9 line 11), with one or more tube carriers dipping into the liquid media, but projecting above the liquid media surface (claim 1), where the carrier tubes are loaded with appropriate media and in contact with the medium in the culture vessel (page 9 lines 19-22), at a temperature of 37 °C to 41.5 °C (page 9, line 23). Holbrook allows the bacteria to move from the liquid media being tested into the supported media during the testing period (claim 1). Holbrook also contemplates at least two supported media in series (claim 3).

Taylor et al. disclose apparatus and methods developed to automatically deliver samples to reaction vessels, analytical devices or any location where sample introduction is desired (page 2, lines 8-12). They use channels, e.g., capillaries, with temperature control devices in communication with the channels allowing the heating/cooling of the capillaries to control the movement of the reagents via pressure changes (page 2). As well, they contemplate the use of one or more temperature control devices to heat and/or cool the entire capillary or discrete locations (page 3, lines 8-12). In paragraph three on pages three, Taylor et al. disclose the theory behind the use of temperature controls and temperature changes. They reveal that “an aliquot of

Art Unit: 1657

sample is drawn into the capillary to fill the volumetric void left by the contracting gas when the system is cooled” (page 3, line 22). They particularly disclose a preferred embodiment wherein a sample delivery system is used to introduce a sample into a sample analysis apparatus (page 3, lines 29-31).

Grant et al. teach a “method for analyzing solid material in a liquid sample, which comprises the steps of: substantially uniformly distributing the sample by passage through a plurality of discrete wells provided in an integral member and whose bases are defined by filter material that retains the solid material and allows the passage of liquid, the concentration of solid material being such that it is absent in at least one well; and analyzing the wells for the presence of retained solid material” (claim 1). As well as a “device adapted for use in a method for analyzing solid material in a liquid sample comprises the combination of: a container for the sample; a unit comprising a number of discrete wells adapted to retain the solid material and allow the passage of liquid under the application of reduced pressure; structure for drawing liquid from the container and through the wells under reduced pressure; and a manifold or other element that provides uniform distribution of the sample passing from the container into the wells” (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Holbrook, Taylor et al. and Grant et al. to achieve the invention as described. Separation of a sample for the purposes of analyzing a suspected microbacterial component is described by both Holbrook and Grant et al. While Holbrook teaches allowing the bacteria to move into the test system under their own motile power, Grant et al. teach using reduced pressure created by suction and Taylor et al. teach using heating and

Art Unit: 1657

cooling to create the pressure gradients necessary to move liquid samples among test containers. Each of these references teaches that the sample containers must be open to each other, to allow movement of the samples to be tested, and each teaches a variety of temperatures for the assays, as well as Taylor et al. teaching the use of heating and cooling temperatures to control the pressure of the containers and the movement of the sample fluids. One would be motivated to do sample testing assays and have a reasonable expectation of success because of the importance to the health care community and pharmaceutical industry of selective testing for bacteria and the specificity of the teachings of the cited references, among many others, disclosing the mechanics of selective bacterial assays.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh